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1. Contractor agrees to provide to the Department of Health Services (DHS) the services described herein:

   Sections 3380-3390 of the Health & Safety Code, Chapter 435, requires immunizations against childhood diseases prior to school admittance. Health Officers are required to organize and maintain a program to make the required immunizations available. This contract assists the Contractor in defraying costs of the program which supports the State's objectives to control diseases that are preventable by vaccines. It is the Department of Health Services' responsibility to provide this assistance to the local health jurisdictions. The Contractor is to conduct a general immunization program which provides rubella, measles, mumps, polio, diphtheria, tetanus, pertussis, haemophilus influenzae b, and hepatitis B vaccines to the general public. In addition, the Contractor identifies target populations in need of immunizations and initiates corrective action to improve immunization levels.

2. The services shall be performed at applicable facilities in the County of xxx.

3. The services shall be provided during County working hours and days.

4. The project representatives during the term of this agreement will be:

Department of Health Services	**Contractor**
xxx xxx	

Direct all inquiries to:

Department of Health Services	**Contractor**
Immunization Branch Attention: Leona O'Neill 2151 Berkeley Way, Room 712 Berkeley, CA 94704	County of xxx (Health and Human Services Agency)

Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this agreement.

5. SERVICES TO BE PERFORMED – Pediatric-IAP-Hepatitis B

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The Contractor must agree to the following inclusive objectives and conduct the following activities. Please note that many of these services to be performed are also objectives and activities required by the Federal Government and are conditions for funding of the California Immunization Program and/or statutory requirements of State and local health departments. The level of subvention contract funding to be awarded is not represented as sufficient for support of all the required activities; a significant amount of local support and funding is expected. Subvention contract funds must not be used to supplant (i.e., replace) local funds currently being expended for routine immunization services and activities. Subvention funds can only be used for the activities outlined in the budget justification.

A. Objectives:

1) Raise to (or maintain) immunization levels of 95% or greater for each of the legally required immunizations among all kindergarten entrants, incoming transfer students to schools, and entrants into child care centers within the Contractor's jurisdiction.

2) By the year 2005, 90% of two-year-olds within the Contractors jurisdiction should be vaccinated with one dose of measles, mumps, and rubella (MMR) vaccine, three doses of polio vaccine, at least four doses of diphtheria, tetanus, and pertussis (DTP) vaccine, three doses of *Haemophilus influenzae* type b (Hib) vaccine, three doses of hepatitis b vaccine, and one dose of varicella vaccine.

3) Through prevention, surveillance and outbreak control, reduce, and if possible eliminate, illness, disability and death due to vaccine preventable diseases such as polio, diphtheria, tetanus, pertussis, measles, rubella, mumps, hepatitis B, hepatitis A, Haemophilus Influenzae Type b, and varicella within the Contractor's jurisdiction.

4) Establish and/or maintain an effective reminder/recall system for clinic patients which includes the following elements:

   a. Reminder system (postcard, telephone call, or autodialer)
   b. Follow up recall notices for no - shows
   c. Simple tracing procedures for missing clients
   d. Written protocol

5) Inform and educate health care providers, school staff, child care community, and the general public about the need for scheduled timely immunizations of children and adults.

B. Specific Activities:

1) <u>Program Management</u>

   a. Contractor agrees to assign one or more staff the responsibility of monitoring each program activity 1) Program Management; 2) Service Delivery; 3) Population Assessment; 4) Surveillance and Outbreak Control; 5) Provider Quality Assurance; 6) Consumer Information; 7) Immunization Registries; and (8) Vaccine Management.

   b. Contractor agrees to coordinate program planning and implementation of strategies to improve immunization coverage rates of the population with local public and private agencies, e.g., WIC, CHDP, CALWORKS, Healthy Families, medical societies, non-profit community based organizations, and other public agencies serving adults and children located in the health jurisdiction.

2) <u>Service Delivery</u>

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a. Public immunization clinic policies and practices shall be in general accordance with the current recommendations approved by the U.S. Public Health Service and endorsed by the American Academy of Pediatrics (AAP) as specified in the *Standards for Pediatric Immunization Practices. Appropriate in-service training for public clinic staff shall be instituted to assure compliance with the Standards.

b. Within the health jurisdiction, the Contractor shall ensure those medically underserved children, adolescents and adults utilize a medical home to facilitate continuity of care, including receipt of all recommended immunizations.

c. Within the health jurisdiction, the Contractor shall implement and maintain immunization clinic reminder/recall systems among all public medical providers, who receive state-supplied vaccines, to improve age-appropriate immunizations of preschool-age children.

d. Public health clinics with a CASA (4 DTP, 3 polio, 1 MMR, 3 Hib and 3 Hepatitis B) rate below 40% should achieve a 25% improvement; public health clinics with rates between 40% and 49% should achieve a 15% improvement; public health clinics with rates between 50% and 69% should achieve a 10% improvement; and public health clinics with rates between 70% and 85% should achieve a 5% improvement.

3) Population Assessment

a. In accordance with the guidelines and timetables provided by the Immunization Branch, the Contractor shall coordinate the assessment of the immunization levels of child care centers, Head Start Centers, kindergarten, and 7th grade entrants.

b. In coordination with Immunization Branch Field Representatives, local health authorities and local child care center and school authorities, the Contractor must make efforts to ensure that all (100%) child care centers, Head Start centers and schools fully enforce existing regulations pertaining to the immunization of children admitted to such institutions.

c. In accordance with the guidelines and timetables provided by the Immunization Branch, the Contractor shall conduct selective review assessments of randomly selected child care centers, Head Start centers and schools to ensure enforcement of existing immunization regulations pertaining to the immunization of children admitted to such institutions

4) Surveillance and Outbreak Control

a. Contractor shall establish and maintain an effective system for identification and reporting of suspect, probable and confirmed cases of vaccine preventable diseases (VPDs). Sources of surveillance information should include practicing physicians, licensed laboratories, outpatient clinics, hospitals, schools, child care centers and Head Start centers. As necessary, contractor shall conduct enhanced, active surveillance in communities where a VPD is prevalent.

b. Investigation and Control of VPDs

i. Investigation of all reported suspect, probable and confirmed VPDs shall be initiated in accordance with the guidelines and timetables provided by the Immunization Branch.

ii. Outbreak control procedures for the VPDs shall be initiated in accordance with the guidelines and timetables of the Immunization Branch.

c) Contractor shall participate in the national Vaccine Adverse Events Reporting System (VAERS) for follow up of adverse events following immunizations in accordance with current Immunization Branch guidelines.

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5) Provider Quality Assurance

a) Assure that health care providers within the jurisdiction are knowledgeable and competent in immunization practices. Provide and/or promote training opportunities. Such opportunities may include live training/educational courses, distance learning satellite courses, grand rounds and medical meeting presentations, seminars, health officer newsletters, exhibits, workshops, in-service training, medical assistant training, provider site visits, and distribution of informational, educational, or practice management materials to physicians in practice.

b) Annually, within the health jurisdiction, the Contractor shall review immunization records of select public clinics that receive state-supplied vaccine. The sampling technique and immunization clinic record methodology must be compatible with the methodology of the Immunization Branch of the California Department of Health Services.

c) As funding permits, the Contractor shall conduct quality assurance reviews and record assessments of private health care providers enrolled in the California Vaccines for Children Program.

6) Consumer Information

a) To reach families in the community and reduce ethnic disparities in immunization rates, the Contractor will promote and implement outreach activities through partnerships, coalitions, and collaboration with community groups, childcare providers, and culturally specific organizations.

b) The Contractor will ensure that each maternity hospital within the jurisdiction has a new mother education program. Types of programs include distribution of the Hallmark Card, distribution of pertinent languages of Parent's Love Cards, and Baby Track-type reminder programs. Including immunization information in Registrar of Births mailings to new mothers also is encouraged.

7) Immunization Registries

a) As funding permits, design and construct an immunization registry in accordance with the 12 CDC – DHS Immunization Branch 12 functional standards of operation.

b) As funding permits, collaborate with provider organizations and other stakeholders in the registry's catchment area to assist with provider recruitment, planning and implementation.

c) As funding permits and once registry is operational, increase the percentage of public and private provider sites participating in the registry.

8) Vaccine Management

The contractor receiving vaccine purchased with State of California/Federal funds, herein called State purchased vaccines, agrees to the following terms and conditions.

a) Prior to receipt of an immunization, all patients (or their parents or legal guardians) must be:

i. screened in accordance with the federal Centers for Disease Control and Prevention (CDC) and Health Care Finance Administration (HCFA) requirements to determine their eligibility for receipt of vaccine from the federal Vaccines for Children Program;

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ii. provided a copy of the current "Vaccine Information Statement" for each vaccine dose to be administered (in the case of hepatitis B vaccine given to newborn infants this can be provided to the mother during prenatal care or within 12 hours after delivery);

iii. provided a reasonable opportunity to read the "Vaccine Information Statement(s)";

iv. provided an opportunity to ask questions and have questions answered concerning the benefits and risks of each immunization;

v. specifically asked if they understand the information provided to them and if they have any questions;

vi. given a telephone number to call should the patient become ill and have to visit a physician, clinic or hospital within the 28 days following the immunization;

vii. provided the authorized appropriate translations of the "Vaccine Information Statements" if English is not their first language and their language is one for which the State has made translations available.

The Immunization Branch will supply to all local health departments camera-ready copies and/or a supply of the "Vaccine Information Statements" in English and Spanish. In addition, should a sufficient need exist, the Immunization Branch will arrange for authorized translations and provide camera-ready copies and "Vaccine Information Statements" in other languages.

b) Health care providers must make notation in each patient's permanent medical record at the time the "statements" are provided. For health care providers who obtain vaccine via federal contract, the CDC Immunization Grant Guidance defines this as (1) date printed on the appropriate "Vaccine Information Statement(s)" and (2) date the "Vaccine Information Statement(s)" was given to the vaccine recipient, parent, or legal representative.

The record card or log sheet must include as a minimum the following information:

i. patient name
ii. address
iii. date of birth
iv. age at time of immunization
v. type of vaccine(s) given
vi. clinic identification
vii. date of immunization
viii. site of immunization
ix. name and title of person administering the vaccine (e.g., S. Smith, R.N.)
x. vaccine manufacturer
xi. vaccine lot number
xii. *signature of patient or parent/guardian authorizing immunization (optional)*
xiii. *date of signature (optional)*
xiv. date(s) printed on the "Important Information" statement(s) and/or "Vaccine Information Statements" provided to the patient or parent/guardian

NO ALTERATION, VARIATIONS OR ADDITIONS TO THE IMPORTANT INFORMATION STATEMENTS, VACCINE INFORMATION STATEMENTS, OR VACCINE AGREEMENT MAY BE MADE WITHOUT THE PRIOR WRITTEN APPROVAL OF THE CHIEF OF THE IMMUNIZATION BRANCH OF THE CALIFORNIA DEPARTMENT OF HEALTH SERVICES.

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c) The authorized immunization patient record or authorized clinic log sheets must be stored by the local health department in a retrievable file for a minimum of 10 years following the end of the calendar year in which the statement was provided to the vaccine recipient, parent, or legal representative. In addition, if a notice of a claim or lawsuit has been made, the record must be retained until after a final disposition has been made.

d) In the case of a school-based program, or other programs where the "Vaccine Information Statement(s)" are to be read in advance of the immunization by the patient or parent/guardian or other authorized person who will not be present at the site where the immunizations are to be given, procedures shall be established and made known for answering questions by telephone.

e) Outside non-profit providers of immunization services must sign the State provided "Outside Provider Agreement for Receipt of State-Supplied Vaccines" terms prepared by the State Immunization Branch before they may receive State purchased vaccine. Medical providers of immunization services who sign the agreement must agree to use the "Vaccine Information Statements" and must be provided as many copies of the statements as vaccine doses distributed, or at least one camera-ready copy of each vaccine statement. The "Outside Provider Agreement..." and the use of the "Vaccine Information Statements" are required in clinic settings even if the clinics are supervised by a physician in attendance. The "Outside Provider Agreement..." shall be signed annually by non-health department medical providers and retained by the local health department for a minimum of ten years following the last calendar year in which the State Immunization Branch purchased vaccine was provided.

f) No charge may be made to the patient, parent, guardian or third party payer for the cost of State purchased vaccine provided to local health departments by the Immunization Branch. In addition, outside, non-profit providers of immunization services receiving State purchased vaccine may not charge patients or parents for the cost of vaccine. Charges made by local health departments for the direct costs incurred for administration or injection of the vaccine are discouraged but are not specifically prohibited. Should the health department or outside medical provider receiving state vaccine establish an administration fee for an injection of vaccine, information, e.g., sign/poster, must be prominently displayed which indicates that no one receiving an immunization in a public clinic may be denied vaccine provided through public funds for failure to pay the administration fee or failure to make a donation to the provider.

g) Local health departments and other private and public providers utilizing State purchased vaccine must report quarterly the vaccine doses administered, by vaccine type and age group of patient, and dose in series (for multiple-dose vaccines) in a format provided by the Immunization Branch. Reports should be submitted to the Immunization Branch by the third day of the following month.

h) Each quarter, the local health department must report a current vaccine inventory including all sites within the county or local jurisdiction. The Immunization Branch will supply the reporting forms. All local health departments are to **notify their Immunization Branch Field Representative** of any vaccine which is unlikely to be used not later than three months prior to its date of expiration.

i) The local health department agrees to ensure that the storage and handling of State purchased vaccine within its facilities is in accordance with the manufacturers' specifications. The local health department also agrees to inform other providers who receive Immunization Branch purchased vaccine of the manufacturers' specifications for vaccine storage and handling.

C. Specific Perinatal Hepatitis B Activities (only for contractors receiving federal perinatal hepatitis B funds):

1) Laboratory Reporting - The Contractor Agrees to the following:

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a. Within the health jurisdiction, the Contractor identifies all public and private laboratories performing HBsAg serologic tests.

b. A listing of laboratories performing HBsAg tests in the health jurisdiction is maintained and routinely updated.

c. Identified laboratories are notified that positive HBsAg tests of females ages 10 - 44 are to be reported biweekly to the local health department.

d. Delinquent laboratories not reporting HBsAg tests are contacted and informed of reporting requirements.

2) Case Management of Identified HBsAg Pregnant Women - The Contractor Agrees to the Following:

a. A Case Management Report is initiated on all pregnant women (public and private sector) with positive HBsAg laboratory test results of pregnant women.

b. From the reported positive HBsAg, the medical provider (obstetrician, family M.D., midwife, etc.) who requested the HBsAg test is contacted by the Contractor to determine the following:

- The expected date of delivery of the infant.
- Hospital where delivery is planned.
- Have arrangements been made with pediatrician or family physician to ensure the newborn receives HBIG and the 1st dose of hepatitis B vaccine in the hospital?
- Status of household contacts is or will be determined, i.e., screening and immunization of susceptibles.
- Does female/family income status permit Medi-Cal or other third party reimbursement for the HBsAg screening test, infant HBIG dose, and subsequent hepatitis B immunizations?
- Does the medical provider request or grant permission to the local health department to case manage the positive female, infant, and household contacts?

3) Follow-up and Immunization of Infants and Susceptible Household Contacts - The Contractor Agrees to the following:

a. Infants born to HBsAg positive women receive HBIG and 1st dose of hepatitis B vaccine within 12 hours after birth or before discharge from the hospital. Subsequently, the infants receive the 2nd and 3rd doses in accordance with United States Public Health Service Immunization Practices Advisory Committee (ACIP) schedule.

b. Household contacts are screened and the susceptibles identified receive the three dose regimen of hepatitis B vaccine in accordance with the ACIP schedule.

c. For public sector women, during the follow up of the mother, infant, and contacts, the medical provider(s) is instructed to submit claim(s) for reimbursement of tests and vaccine for recipients eligible for the State Medi-Cal Program or other third party payment.

4) Laboratory Screening - The Contractor Agrees to the following:

a. The Contractor will make efforts to ensure that laboratory screening for HBsAg and core anti-body (anti-HBc) is reimbursed by Medi-Cal or other third party payers.

b. The Contractor will offer or provide the means for public HBsAg and core anti-body (anti-HBc) tests for pregnant women and household contacts who are not determined to be eligible for Medi-Cal or other third party reimbursement.

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5) Information and Education - The Contractor Agrees to the following:

a. Professional

- Appropriate physicians and hospitals will be provided information emphasizing California State Law requires prenatal HBsAg screening for all pregnant women.
- All obstetric hospitals will be informed of the need for a hospital policy to ensure the HBIG and 1st dose of hepatitis B vaccine are provided within 12 hours of birth to the infants at risk born: (i) to women known to be HBsAg-positive; and (ii) to women at high-risk of HBsAg positivity but for whom an HBsAg test result cannot be obtained within 12 hours after birth.
- Health professionals will be informed of the need to provide disease and vaccination information to the contractor for case management and tracking purposes.
- Registered midwives and non-hospital birthing centers will be provided information for referral of pregnant women with positive HBsAg tests to the local heath department for follow-up.
- Laboratories, including public health, hospital, and private, which conduct hepatitis B screening tests will be provided information which explains the requirement that all positive tests of women are reported to the local health department.

b. General Public

- Pregnant women who have been identified as hepatitis B carriers will be provided with (i) specific information addressing prevention of transmission to infants and household contacts; and (ii) information about seeking regular health care for themselves relative to their carrier status.
- Organizations, associations, and media serving high risk populations will be provided hepatitis B prevention information for their members and/or audience.
- Household contacts identified as hepatitis B carriers will be provided information about what the infection means for their health as well as addressing prevention of transmission.

D. Required Reports

1) Reports of Local Program Progress and Activities

In accordance with the guidelines and format provided by the Immunization Branch, the Contractor shall submit, **through his/her Immunization Branch District Field Representative,** to the Branch identified in paragraph 5 within D. Required Reports, by the 15th of the month following the end of each quarter, a written quarterly report of progress and activities. In addition to the written report the Contractor and Project Liaison, or his designee, may meet and discuss the above matters in person.

2) Upon completion of the investigation of each probable or confirmed measles case, a completed investigation form must be submitted to the Immunization Branch.

3) Contractor agrees that itemized personnel positions listed in the *Application for Immunization Project Subvention Funds* shall not be subject to Contractor's personnel policy decisions to refrain from filling vacant positions.

4) The Contractor shall submit **through his/her Immunization Branch District Field Representative,** to the Branch identified in paragraph 5 within D. Required Reports, on or before the 3rd of the month following the report month, a written Monthly Vaccine Usage Report in the form prescribed by the State Department of Health Services, Immunization Branch.

5) All reports, other than those required to be directed to the District Field Representatives, invoices, and other written communications are to be addressed and delivered to the State Department of Health Services, Immunization Branch, 2151 Berkeley Way, Berkeley, California 94704.

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6) The State reserves the right to use and reproduce all reports and data produced and delivered pursuant to this Contract and reserves the right to authorize others to use or reproduce such materials, provided that the confidentiality of patient information and records are protected pursuant to California State laws and regulations.

7) It is agreed by the Contractor that in the event that a significant portion of the Contract objectives for the initial four months of the Contract are not met by that time; and in the event that the State determines from quarterly invoices, performance reports, and other sources of information that the Contractor will not perform the total quantity of services contracted for; and that therefore, the total budget allocation will not be depleted; the State and/or Contractor may make an equitable adjustment in the original Contract budget and Contract objectives in order to decrease the total quantity of services and commensurate Contract amount. Any adjustment shall be by amendment only and duly executed by both parties and approved by the Department of General Services (if applicable).

8) In accordance with State Immunization Branch protocol and guidelines for Vaccines for Children (VFC) Quality Assurance Review/CASITA visits, the Contractor agrees to conduct **10** visits at identified private sites in the health jurisdiction during Calendar Year 2002. Within thirty (30) calendar days of completing each visit, a written report of findings will be provided to the assigned District Area Immunization Branch Field Representative.